



Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: May 14, 2009

TO: All Local Health Departments
Attn: Chief Food Specialist

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: AS Medications Solution LLC. - Recall of All Lots of Digoxin Tablets 0.25mg

Suggested Action: **CLASS Unidentified; All Lots of Digoxin Tablets 0.25mg Due to Size Variability; Recommend notification to establishments that may carry these products via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. Caraco Pharmaceutical Laboratories, Ltd manufactured the recalled tablets. These items were distributed nationwide. Detail information is not available at this time. Please notify this office at 317-233-7360 if any recalled product is found.

AS Medications Solution LLC. Announces a Nationwide Recall of All Lots of Digoxin Tablets 0.25mg Due to Size Variability

Contact:
Bill Norkus
(847) 680-3515

FOR IMMEDIATE RELEASE -- Libertyville, IL, May 11, 2009 – A S Medication Solutions, LLC, a drug repackaging company, announced today that all tablets of Caraco brand Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009, which are not expired and are within the expiration date of August, 2011, are being voluntarily recalled to the consumer level. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. Caraco Pharmaceutical Laboratories, Ltd manufactured the recalled tablets. This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Digoxin is a drug product used to treat heart failure and abnormal heart rhythms. It has a narrow therapeutic index and the existence of higher than labeled dose may pose a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability, and slow heart rate. Death can also result from excessive digoxin intake. A lower than labeled dose may pose a risk of heart failure and abnormal heart rhythms.. Consequently, as a precautionary measure, A S Medication Solutions, LLC is recalling these tablets to the consumer level to minimize any potential risk to patients.

Consumers with the products with the following NDC codes that are within expiration should return these products to the place of purchase.

Product Identification

Caraco Digoxin

A-S Medication Solutions, Digoxin 0.25 mg is a scored round biconvex white tablet imprinted with "441"

NDC Numbers:

Digoxin Tablets, USP, 0.25 mg

54569-5758-0 (30-count)

Patients using A-S Medication Solutions, Digoxin tablets, USP, 0.25 mg, who have medical questions should contact their healthcare provider for additional instructions or guidance.

Healthcare providers who have this product should return the product to their place of purchase. Healthcare providers can call A-S Medication Solutions Recall Coordinator at (847) 680-3515, Monday through Friday, 8:00 a.m. – 4:00 p.m. CST, for instructions on how to return the affected product or for any other inquiries related to this action.

Any adverse reactions experienced with the use of all affected product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at Med Watch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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